

ATTACHMENT #1

## **Adverse Event Reporting System (AERS)**

**Freedom Of Information (FOI) Report**

**Selections for:           NOINGRED  
                                  NUTROPIN\_DEPOT**

**From:   01-NOV-1997   To:   Present**

Disclaimer: The information contained in these reports has not been scientifically or otherwise verified as to a cause and effect relationship and cannot be used to estimate the incidence of adverse drug reactions.

# FDA - Adverse Event Reporting System (AERS)

## Freedom Of Information (FOI) Report

Date: 11/01/00 ISR Number: 3609824-1 Report Type: Periodic Company Report#: 095952 Age: 24 MON Gender: I/FU: 1

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Injection Site Oedema Injection Site Reaction Nos Leukocytosis Pyrexia Rash Erythematous Red Blood Cell Sedimentation Rate Increased White Blood Cell Count Increased	Health Professional Company Representative	Nutropin Depot	PS	Genentech Inc			

Date: 11/01/00 ISR Number: 3609826-5 Report Type: Periodic Company Report#: 095995 Age: 80 YR Gender: Male I/FU: 1

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Injection Site Erythema Injection Site Inflammation Injection Site Oedema Injection Site Pain	Health Professional	Nutropin Depot	PS	Genentech Inc			

Date: 11/01/00 ISR Number: 3609827-7 Report Type: Periodic Company Report#: 096018 Age: 3 YR Gender: Female I/FU: 1

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Headache Nos Injection Site Mass Pyrexia	Health Professional	Nutropin Depot Antibiotics Stool Softener	PS C C	Genentech Inc	SUBCUTANEOUS	16 MG SC	

Date: 02/27/01 ISR Number: 3670973-3 Report Type: Direct Company Report#: Age: Gender: Female I/FU: 1

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening Hospitalization - Initial or Prolonged Disability	Diabetes Mellitus Insulin-Dependent		Nutropin Depot 18 Mg Somatropin Genentech, Inc	PS	Genentech, Inc	SUBCUTANEOUS	.75MG/KG ARMS/LEGS SUBCUTANEOUS	

Date: 05/01/01 ISR Number: 3714927-7 Report Type: Periodic Company Report#: 097634 Age: 9 YR Gender: Male I/FU: 1

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Diabetes Mellitus Aggravated	Distributor	Nutropin Depot	PS	Genentech Inc	SUBCUTANEOUS	22.5 MG 2/M SC	

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## Freedom Of Information (FOI) Report

Date: 07/10/01    ISR Number: 3755886-0    Report Type: Expedited (15-Day)    Company Report#: 098411							Age: 10 YR	Gender: Male	I/FU: 1
<u>Outcome</u> Hospitalization - Initial or Prolonged	<u>PT</u> Abdominal Pain Upper Dehydration Headache Nos Pyrexia Vomiting Nos Weakness	<u>Report Source</u> Consumer Company Representative	<u>Product</u> Nutropin Depot	<u>Role</u> PS	<u>Manufacturer</u> Genentech Inc	<u>Route</u> SUBCUTANEOUS	<u>Dose</u> 31.5 MG 2/M SC	<u>Duration</u>	
Date: 07/10/01    ISR Number: 3755887-2    Report Type: Expedited (15-Day)    Company Report#: 098412							Age: 10 YR	Gender: Male	I/FU: 1
<u>Outcome</u> Hospitalization - Initial or Prolonged	<u>PT</u> Dehydration Pyrexia Vomiting Nos White Blood Cell Count Increased	<u>Report Source</u> Consumer Company Representative	<u>Product</u> Nutropin Depot  Nutropin Depot	<u>Role</u> PS  SS	<u>Manufacturer</u> Genentech Inc	<u>Route</u> SUBCUTANEOUS	<u>Dose</u> 31.5 MG 2/M SC	<u>Duration</u>	
Date: 08/03/01    ISR Number: 3772546-0    Report Type: Periodic    Company Report#: 097634							Age: 9 YR	Gender: Male	I/FU: F
<u>Outcome</u> Life-Threatening	<u>PT</u> Diabetes Mellitus Aggravated	<u>Report Source</u> Distributor	<u>Product</u> Nutropin Depot	<u>Role</u> PS	<u>Manufacturer</u> Genentech Inc	<u>Route</u> SUBCUTANEOUS	<u>Dose</u> 22.5 MG 2/M SC	<u>Duration</u>	
Date: 08/15/01    ISR Number: 3778233-7    Report Type: Expedited (15-Day)    Company Report#: 098873							Age: 18 MON	Gender: Female	I/FU: 1
<u>Outcome</u> Hospitalization - Initial or Prolonged	<u>PT</u> Dehydration Diabetes Mellitus Inadequate Control Diarrhoea Nos Irritability Markedly Reduced Dietary Intake Pyrexia Urinary Tract Infection Nos Vomiting Nos	<u>Report Source</u> Health Professional	<u>Product</u> Nutropin Depot Ddvp Thyroxine	<u>Role</u> PS C C	<u>Manufacturer</u> Genentech Inc	<u>Route</u>	<u>Dose</u> 6.75 MG QM SC	<u>Duration</u>	
Date: 11/21/01    ISR Number: 3828526-X    Report Type: Expedited (15-Day)    Company Report#: 099202							Age: 11 MON	Gender: Male	I/FU: F
<u>Outcome</u> Death Life-Threatening Hospitalization - Initial or Prolonged	<u>PT</u> Cardio-Respiratory Arrest Loose Stools Respiratory Distress Sepsis Nos Vomiting Nos	<u>Report Source</u> Study Health Professional	<u>Product</u> Nutropin Depot	<u>Role</u> PS	<u>Manufacturer</u>	<u>Route</u> SUBCUTANEOUS	<u>Dose</u> 5.25 MG 2/M SC	<u>Duration</u>	

# FDA - Adverse Event Reporting System (AERS)

## Freedom Of Information (FOI) Report

Date: 12/12/01 ISR Number: 3840288-9 Report Type: Expedited (15-Day) Company Report#: 100372

Age: 3 YR

Gender: Female

I/FU: I

<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose</u>	<u>Duration</u>
Hospitalization - Initial or Prolonged	Abdominal Pain Nos Diarrhoea Nos Lethargy Loose Stools Pyrexia Vomiting Nos	Consumer	Nutropin Depot Antituberculosis Medications	PS  C				

Date: 06/03/02 ISR Number: 3928709-4 Report Type: Expedited (15-Day) Company Report#: 102636

Age: 12 YR

Gender: Female

I/FU: I

<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose</u>	<u>Duration</u>
Disability Other	Antinuclear Factor Positive Arthralgia Difficulty In Walking Rheumatoid Factor Positive	Study Health Professional	Nutropin Depot  Prednisone Neoral Furosemide Atenolol Diltiazem Famotidine Feso4 Calcitriol Lovastatin Zolofit Probenecid Allopurinol	PS  C C C C C C C C C C C C		SUBCUTANEOUS	40.5 MG Q2WK SC	

Date: 08/21/02 ISR Number: 3966779-8 Report Type: Expedited (15-Day) Company Report#: 103750

Age: 15 YR

Gender: Male

I/FU: I

<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose</u>	<u>Duration</u>
Life-Threatening Hospitalization - Initial or Prolonged Required Intervention to Prevent Permanent Impairment/Damage	Glioblastoma	Study Health Professional	Nutropin Depot	PS		SUBCUTANEOUS	37.5 MG Q3WK SC	

Date: 09/05/02 ISR Number: 3972561-8 Report Type: Expedited (15-Day) Company Report#: 103750

Age: 15 YR

Gender: Male

I/FU: F

<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose</u>	<u>Duration</u>
Life-Threatening Hospitalization - Initial or Prolonged Required Intervention to Prevent Permanent Impairment/Damage	Anaplastic Astrocytoma Neuroblastoma Nos	Study Health Professional	Nutropin Depot  Testosterone	PS  C		SUBCUTANEOUS	37.5 MG Q2WK SC	

**FDA - Adverse Event Reporting System (AERS)**  
**Freedom Of Information (FOI) Report**

Date: 10/10/02 ISR Number: 3991092-2 Report Type: Direct Company Report#: CTU 178499 Age: 9 YR Gender: Female I/FU: 1

<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose</u>	<u>Duration</u>
Life-Threatening Hospitalization - Initial or Prolonged Disability	Diabetes Mellitus Insulin-Dependent		Nutropin Depot 18 Mg Genentech, Inc	PS	Genentech, Inc	SUBCUTANEOUS	33 MG EVERY 14 DAYS SUBCUTANEOUS	

Date: 11/07/02 ISR Number: 4008855-X Report Type: Expedited (15-Day) Company Report#: 104671 Age: Gender: Female I/FU: 1

<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose</u>	<u>Duration</u>
Other	Neoplasm Recurrence Nos	Consumer	Nutropin Depot	PS				

Date: 11/18/02 ISR Number: 4013159-5 Report Type: Expedited (15-Day) Company Report#: 102642 Age: 35 YR Gender: Female I/FU: 1

<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose</u>	<u>Duration</u>
Death Life-Threatening	Adrenal Insufficiency Nos Gastroenteritis Viral Nos	Study Health Professional	Nutropin Depot Dilantin Hydrocortisone Prozac L-Thyroxin Ddvap Premarin Provera	PS C C C C C C C		SUBCUTANEOUS	8.4 MG SC	

Date: 12/10/02 ISR Number: 4024753-X Report Type: Expedited (15-Day) Company Report#: 105035 Age: 11 YR Gender: Male I/FU: 1

<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose</u>	<u>Duration</u>
Hospitalization - Initial or Prolonged	Convulsions Nos Dilatation Ventricular Fall Pneumonia Nos Tibia Fracture		Nutropin Depot Topamax	PS C		SUBCUTANEOUS	45 MG 12WK SC	

Date: 01/07/03 ISR Number: 4040228-6 Report Type: Expedited (15-Day) Company Report#: 105263 Age: 12 YR Gender: Male I/FU: 1

<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose</u>	<u>Duration</u>
Life-Threatening Hospitalization - Initial or Prolonged Required Intervention to Prevent Permanent Impairment/Damage	Adrenal Insufficiency Nos Blood Glucose Decreased Gastroenteritis Viral Nos Lethargy Loss Of Consciousness	Study Health Professional	Nutropin Depot  Cortef Synthroid	PS  C C		SUBCUTANEOUS	22.5 MG Q2WK, SC	

Date: 02/24/03 ISR Number: 4064902-0 Report Type: Expedited (15-Day) Company Report#: 105888 Age: 25 YR Gender: Female I/FU: 1

<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose</u>	<u>Duration</u>
Hospitalization - Initial or Prolonged	Bradycardia Nos Hypokalaemia Nausea							

# FDA - Adverse Event Reporting System (AERS)

## Freedom Of Information (FOI) Report

Pharyngolaryngeal Pain  
Supraventricular  
Tachycardia  
Vomiting Nos

Report Source  
Health  
Professional

Product  
Nutropin  
Depot(Somatropin)

Role Manufacturer  
PS

Route Dose Duration  
SUBCUTANEOUS 67.5 MG,  
SINGLE,  
SUBCUTANEOUS

Date: 03/12/03 ISR Number: 4075452-X Report Type: Expedited (15-Day) Company Report#: 200076

Age: 13 YR Gender: Male I/FU: 1

<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose</u>	<u>Duration</u>
Death	Death Unexplained Vomiting Nos	Health Professional	Nutropin Depot(Somatropin) Pwdr & Solvent, Injection Soln	PS			16 5 MG	

Date: 03/21/03 ISR Number: 4081934-7 Report Type: Expedited (15-Day) Company Report#: 096413

Age: 10 YR Gender: Female I/FU: 1

<u>Outcome</u>	<u>PT</u>	<u>Report Source</u>	<u>Product</u>	<u>Role</u>	<u>Manufacturer</u>	<u>Route</u>	<u>Dose</u>	<u>Duration</u>
Hospitalization - Initial or Prolonged Disability	Blood Thyroid Stimulating Hormone Increased Diabetes Mellitus Nos Diabetic Ketoacidosis	Study Health Professional	Nutropin Depot (Somatropin) Pwdr & Solvent, Injection Soln	PS		SUBCUTANEOUS	33 MG, QD, SUBCUTANEOUS	